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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/002,196	12/05/2001	Tianxin Wang	3889-0101P	2451

7590 05/03/2004

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EXAMINER	
DI NOLA BARON, LILIANA	
ART UNIT	**PAPER NUMBER**
1615	

DATE MAILED: 05/03/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/002,196	WANG ET AL.	
	Examiner	Art Unit	
	Liliana Di Nola-Baron	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 February 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *4-7,12-15,18 and 19* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *4-7, 12-15, 18 and 19* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Receipt of Applicant's response, filed on February 11, 2004, is acknowledged.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 4-7, 12-15, 18 and 19 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. 112, first paragraph, have been described in re Wands, 8 USPQ2d 1400 (Fed. Cir. 1988). Among these factors are: (1) the nature of the invention; (2) the state of the prior art; (3) the relative skill of those in the art; (4) the predictability or unpredictability of the art; (5) the breadth of the claims; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary. When the above factors are weighed, it is the examiner's position that one skilled in the art could not practice the invention without undue experimentation.

(1) The nature of the invention:

The invention is directed to methods for inactivating pathogens, preventing transmission or infection of sexually transmitted diseases, or treating and preventing bacterial vaginitis, comprising administering a composition comprising polyvinyl phthalate sulphate or a salt thereof.

(2) The state of the prior art

The prior art (Bellettini et al.) teaches that sulfonated styrene maleic anhydride copolymers have anti-viral activity against HIV. There is no known art, wherein a certain composition is administered to successfully inactivate pathogens or prevent diseases before their occurrence. Additionally, there is no known art, wherein a certain composition is administered immediately after sexual activity or sexual contact to successfully prevent transmission or infection of sexually transmitted diseases, because by the time the composition is administered transmission of the disease may have occurred already. Administration of the composition after sexual activity or sexual contact might only help reduce transmission of the disease.

(3) The relative skill of those in the art

The relative skill of those having a Ph.D. in the biochemical arts or an M.D. is high.

(4) The predictability or unpredictability of the art

The unpredictability of diseases caused by pathogens, including sexually transmitted diseases and bacterial vaginitis, is very high. For example retroviruses, and especially HIV, are refractory to anti-viral therapies, because of their extensive genomic diversity and mutation rate,

their transmission mode and the complexity and variation of the pathology of HIV infection in different individuals. The lower the predictability, the higher the direction and guidance that must be provided by Applicant. Furthermore, there is no correlation between the pathogens causing the diseases claimed by Applicant: HIV is transmitted to cells as well as via free virus transmission; chlamydia is a gram-negative intracellular bacteria; herpes and papilloma are viruses; syphilis is a disease caused by a spirochete bacteria; gonorrhea is a disease caused by the gonococcus bacteria. The pathogenesis of each organism is different and infection or transmission by the different pathogens involves mechanisms, which are not related. Bacterial infection is different from viral infection. There is no evidence in the specification that established correlation between the different diseases caused by the different pathogens, thus the effect of the composition of Applicant's invention cannot be predicted a priori, but must be determined from the case to case. Additionally, there is no evidence in the specification that the compound used in Applicant's invention interacts with the CD4 receptor to inhibit HIV infection, or affects HIV replication, similar to the drug AZT.

(5) The breadth of the claims

The method claims are very broad. The claims encompass inactivation of any pathogen or prevention of transmission or infection of any sexually transmitted disease or treatment or prevention of bacterial vaginitis, regardless of the pathogen and pathogenesis involved. Claims 4-6, 12-14, 18 and 19 read on administration of the compound by any route. The safety of the compound compositions administered by any route, as claimed by Applicant, is questionable.

The models in the examples of the specification are directed to topical administration, however, claims 4-6, 12-14, 18 and 19 are not limited to topical administration of the compound.

(6) The amount of direction or guidance presented

The amount of direction and guidance provided by Applicant is limited to model systems based on the use of cell lines. Cultured cell lines generally differ significantly from in vivo animal models, and in vitro assays cannot duplicate the complex conditions of in vivo therapy. In the assays, the compound is in contact with the cell lines during the entire exposure period. This is not the case in vivo, where exposure to the target site may be delayed or inadequate. In addition, variables such as biological stability, half-life or clearance from the blood are important parameters in achieving successful therapy. The compound must be delivered into the circulation of an animal in sufficient concentration and for a sufficient period of time to provide the animal with a therapeutic effect. The compound may be inactivated in vivo before producing the desired effect, or may not otherwise reach the target because of its inability to penetrate tissue or cells. Thus there is no evidence in the specification that established correlation between the experiments and the claimed utility.

(7) The presence or absence of working examples

The working examples present no data on the effect of the compositions of the invention on the treatment of the various diseases in vivo.

(8) The quantity of experimentation necessary

The effect of the compositions of the invention on the possible treatment of diseases, for which no correlation has been established, cannot be predicted a priori but must be determined from the case to case by painstaking experimental study in vivo. When the above factors are weighed together, one of ordinary skill in the art would be burdened with undue "painstaking experimentation study" to determine a possible treating effect of the compositions and methods claimed in the instant application.

Response to Arguments

3. Applicant's arguments filed on February 11, 2004 have been fully considered but they are not persuasive.

4. Applicant requests claim draft assistance, pursuant to MPEP section 707.07(j). This argument is not persuasive, since Applicant has not amended the claims in response to the rejection of record, and the claims are not patentable. It is recommended to amend the claims to eliminate language such as "inactivating pathogens" and "preventing transmission or infection", and limit the claims to recite methods of treatment for a specific disease. The instant claims are directed to too many diseases for which a relation has not been established.

Conclusion

5. Claims 4-7, 12-15, 18 and 19 stand rejected.

6. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Liliana Di Nola-Baron whose telephone number is 571-272-0592. The examiner can normally be reached on Monday through Thursday, 8:30AM-7:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on 571-272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

April 27, 2004

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
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